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10/551,366	08/29/2006	Robert D. Black	9099.17	3158
20792 7590 11/27/2009 MYERS BIGEL, SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
EXAMINER NGUYEN, HIEN NGOC				
ART UNIT		PAPER NUMBER		
3768				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/551,366

## Applicant(s)

BLACK ET AL.

## Examiner

HIEN NGUYEN

## Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08/04/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 14, 24-33 and 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-23, 34 and 41-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09/29/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 5-7, 10, 13, 15-18, 20-23, 34 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685) in view of Allen et al. (US 4,945,914).

Regarding claims 1-2, 5-7, 10, 13, 17 and 20-22 Mate discloses:

- a target locating and in vivo sensor system used with a therapy delivery and imaging source; (see [0001] and [0009-0014]).
- an external solenoid member; (see [0032-0039] and [0041-0048]).
- at least one implantable wireless unit such as a solenoid, the solenoid held internally in the patient cooperates with the external solenoid to generate a coupling signal having signal strength that varies based on the position of the external solenoid member relative to the implanted unit; see [0041-0048] [0050], [0056-0061]).
- a computer module in communication with the controller comprising computer program code that evaluated the coupling signal strength in

relation to the position of the external solenoid and determines the position of at least one internally implanted unit; (see [0009-0014] and [0053]).

- the system is capable of using the frequency of 500khz-1Mhz. This is just AC frequency supply to the external solenoid. The system can supply frequency in this range to the external solenoid.

Mate use excitation markers and sensors to identify and track the position of the target. Internal excitation marker is located in or near the target. An external excitation source that is remotely excites the markers to produce an identifiable signal.

Mate does not disclose a mechanism configured to controllably move the solenoid external of a patient, a controller configured to direct the movement of the mechanism and the controller is in communication with a power source.

Allen discloses a mechanical arm configured to hold and move a sensor which is a solenoid external of a patient (col. 15, lines 12-27, robot arm element 34 and sensor/solenoid element 40, the internal and external sensors has to have signal coupling in order to determine position of internal sensor). It is inherent the robot arm has a controller configured to direct the movement of the mechanism/robot arm and the robot arm is in communication with a power source because without controller and power source the robot arm can not move.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mate's system to include a mechanism (robot mechanical arm) that is connect to a power source and has a controller to control its movement and the movement of the solenoid external to the patient as taught by Allen because with the robot mechanical arm and sensor/solenoid at its tip surgeon can effectively keep track of the solenoid/fiducial implant inside the body.

Regarding claims 3 and 18, Allen discloses:

- the mechanism is an articulated arm; (see col. 4, lines 9-68).
- the articulated arm is configured to controllably move the solenoid in three dimensions; (see col. 4, lines 9-68).

Regarding claims 15 and 16, it would have been obvious to one of ordinary skill in the art at the time of the invention that Mate's system in view of Allen perform the functions in claims 15 and 16 because the system has to evaluate signal shape and strength coming from internal sensor in order to locate the internal sensor position. As disclose by Allen above in col. 15, lines 12-27, the robot arm is moving through three dimensional spaces to determine the position of the sensor inside the patient body. The robot arm is moving to find the implant and come into contact with the implant.

Regarding claims 23 and 41, the method claim herein is substantially the same in scope as the system in claims 1 and 7 above. The system applied the method. Thus claim 23 and 41 are rejected for at least the same reason as

claims 1 and 7 above. Also see Mate [0009]. He tracks the position of the cancerous target and selectively applies radiation to the target. This is the same method as claim 41.

Regarding claim 42, Mate discloses:

- positioning the patient in an imaging system in a registered position and obtaining an image of the target treatment site and at least one implanted sensor with the patient in the registered position in an imaging system; (see [0060]). The image show target site 12 and markers 30. It is inherent the patient is in a registered position in order to have images of target site and markers.

Allen discloses

- aligning the coupling member to a fiducial marker associated with the imaging system relative to the registered position and obtaining an electrical measurement of signal strength of the coupling signal while the patient is in the registered position and the coupling member is aligned to define the initial spatial position of the at least sensor unit in three-dimensional space; (see col. 15, lines 12-52). The sensor on the tip of the robot arm finds the fiducial implant and touches it. The coupling member is the sensor on the tip and it aligns with the fiducial marker by touching it. Sensor on the tip has to use electrical measurement of signal strength of the coupling signal in order to find the fiducial marker. The sensor unit is the

fiducial marker and the sensor on the tip is aligning with the sensor unit in three dimensional spaces.

Regarding claims 34 and 43-45, the computer program claim herein is substantially the same in scope as the system in claim 1 above. The system of claim 1 runs the computer program in claim 34. Thus claim 34 and 43-45 are rejected for at least the same reason as claim 1 above. Also see Mate [0009], he discloses guiding radiation therapy, selectively transmit radiation dose using implanted sensor. He has to have computer program in order for the system to perform this function.

3. Claims 4, 8-9, 11-12, 19, and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mate et al. (US 2002/0193685), in view of Allen et al. (US 4,945,914) and further in view of Knapp et al. (WO 97/33513).

Regarding claims 4, 8-9, 11-12, 19 and 46-47, Mate and Allen do not explicitly disclose communicating with implanted sensor unit using a bit encoded RF signal, sensors with sensing parameter for temperature and radiation dose.

Knapp discloses:

- the external reader is configured to communicate with the implanted sensor unit using a bit encoded RF signal to communicate with many sensors, by using bit encoded Knapp can identify and separately communicate with each sensor; (see abstract, page 3, lines 1-33, especially lines 4, 10 and 12). The hand held electromagnetic reader is

the external reader. The transmitted encoded data is the bit encoded RF signal. This is wireless encoded data therefore it has to be bit encoded RF signal.

- at least one sensing parameter is a radiation dose for sensing radiation inside a body; (see page 9, lines 30-36).
- at least one sensing parameter is a temperature for sensing temperature inside the body; (see page 9, lines 30-36).
- the plurality of sensor units are configured to relay data regarding radiation dose and temperature to the reader; (see page 9, lines 1-29).

Mate in view of Allen and Knapp provide a therapy system to provide real time dynamic spatial position data and selected internal parameter data of a target region thereto base on data from the at least one sensor and the coupling signal. There has to be a computer program in order for the system to perform this function. Mate and Allen from claims above provide tracking position data from sensor signal which is the same as dynamic spatial position data from sensors and coupling signal and Knapp provided selected internal parameter data such as radiation and temperature from implanted sensor.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Mate's system to include bit encoded RF signal and sensors as taught by Knapp in order to allow the system to identify and separately communicate with sensors for sensing temperature and radiation dose inside the patient body.



### ***Response to Arguments***

Applicant's arguments, see pages 9-13, filed 08/04/2009, with respect to the rejection(s) of claim(s) 1, 23, 15-16, 4, 8-9, 11-12 and 19 under Mates, Allen (US 5,142,930) and Knapp have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Mates, Allen (US 4,945,914) and Knapp. All arguments are addressed in the rejection sections.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HIEN NGUYEN whose telephone number is (571)270-7031. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768